

**REMARKS**

**Claim Amendments**

Claims 53, 69 and 72 have been amended to delete the term “uncultured” and to define the antigen-presenting cells or their precursors by reciting that the antigen-presenting cells or their precursors “have been incubated or processed under conditions that result in an increase of less than about 50% in cell number as compared to the number of cells at the commencement of the incubation or processing, wherein the antigen-presenting cells or their precursors have been removed from a subject.” Basis for this amendment can be found in the specification at page 15, paragraph [0072], lines 26-31.

Claims 53, 69 and 72 have further been amended to recite “and wherein the antigen-presenting cells or their precursors have been contacted with the antigen for less than 8 hours.” Basis for this amendment can be found at least in the specification at page 31, paragraph [0103], line 14 and page 36, paragraph [0120], line 7. Further, the term “express” has been replaced with “present” in these claims, basis for which can be found at least at page 36, paragraph [0120], line 5.

Claim 54 has been amended to delete reference to the term “uncultured” in light of the amendments to claim 53, and further recites that “the antigen-presenting cells or their precursors are contacted with the antigen for less than about 6 hours.” Basis for this amendment can be found at least at page 31, paragraph [0103], line 14 and page 36, paragraph [0120], line 7.

Claims 55, 59, 61, and 71 have been amended to delete the term “uncultured” to conform with the language of amended claim 53. Claims 59 and 61 have been amended to replace the term “are” with “have been” in line with the terms in amended claim 53. Claim 65 has been amended to correct a typographic error and to delete the extra letter “r.”

New claims 73-75 have been added, stating that the antigen-presenting cells or their precursors, are contacted with the antigen for less than about 4 hours, less than about 2 hours, and less than about 1 hour, respectively. Basis for these new claims can be found at least at page 31, paragraph [0103], line 14 and page 36, paragraph [0120], lines 7-8 of the specification.

New claims 76-78 have been added to specify that the antigen-presenting cells or their

precursors are incubated under conditions that result in an increase of less than 20%, less than 10% and less than 5%, respectively. Basis for these new claims can be found at least at page 15, paragraph [0072], lines 28-31.

New claim 79 has been added to further describe the length of the peptides of claim 61, and recites "the length of the peptides is 12 to 20 amino acids." Basis for new claim 79 can be found at least at page 3, paragraph [0013].

Applicant respectfully submits that no new matter has been introduced with these amendments.

### **Restriction Requirements**

Applicant elects with traverse Group I (claims 53-68, drawn to a composition comprising uncultured antigen-presenting cells which have been contacted with an antigen) for prosecution on the merits. Applicant further elects the species "peptides" as the species of antigen, and "peptides that enhance the production of a T-helper lymphocyte response, wherein the length of an individual peptide is 12-20 amino acid residues," as the species of peptide. Claims 53-57, 59-63, 65-68, and 73-79 are believed to read on the elected species. Applicant reserves the right to pursue the subject matter not elected for prosecution in this application in one or more continuing applications.

Applicant respectfully traverses the requirement and submit that in contrast to the Examiner's assertion that the spleen dendritic cells of Gabrilovich *et al.* have not been expanded with cytokines *in vitro*, the antigen-presenting cells of Gabrilovich *et al.* are in fact cultured and activated. Gabrilovich *et al.* teaches incubating splenocytes overnight in complete culture medium (CCM) (RPMI 1640 supplemented with 100 IU/ml penicillin, 0.1 mg/ml streptomycin,  $10^{-5}$  M  $\beta$ -mercaptoethanol, and 10% fetal calf serum) in presence of 10  $\mu$ M peptide. Gabrilovich *et al.* at p. 112, left column, last paragraph. It is now known in the art that simply incubating dendritic cells (*i.e.*, an antigen presenting cell) in cultured medium in the absence of any specific activating treatment conditions is sufficient of the up-regulation of cell surface activation markers including MHC molecules (see Wilson *et al.*, *Blood*, **103**: 2187-2195, 2005, a copy of which is enclosed herewith, note page 2188, right hand column, last two paragraphs from bottom). Hence, the overnight incubation of the cells in the culture medium of Gabrilovich *et al.* would be expected to result in the activation of the cells.

Significantly, Wilson *et al.* further disclose that the number of dendritic cells in the PBMC populations increases over 100% after overnight in culture (see page 2901, left column and Figure 2B). As such, the overnight incubation conditions in the culture medium of Gabrilovich *et al.* would be expected to expand the splenic dendritic cells by 100% or more as compared to the number of splenic dendritic cells at the commencement of the incubation. Furthermore, the spleen dendritic cells taught by Gabrilovich *et al.* were incubated overnight in complete culture medium, which necessarily means that those cells were cultured, not uncultured as recited in the pending claims.

By contrast, Applicant's antigen-presenting cells are "uncultured" as defined in paragraph [0072] of the specification: a population of cells (or a single cell), which have been removed from an animal and incubated or processed under conditions that do not result in the growth or expansion of the cells *in vitro*, or that results in negligible growth or expansion of the cells (*e.g.*, an increase of less than 50%, 40%, 30%, 20%, 15%, 10%, 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2%, 1%, 0.5%, 0.2% or 0.1 % in cell number as compared to the number of cells at the commencement of the incubation or processing).

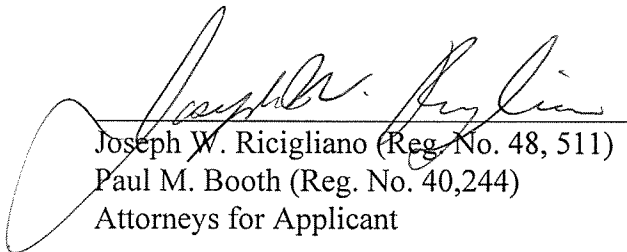
Therefore Applicant respectfully submits that contrary to the Examiner's allegation, Groups I-III do not lack unity of invention because the technical feature of an uncultured antigen-presenting cell is a special technical feature, even in view of Gabrilovich *et al.*

**CONCLUSION**

Applicant believes that this response is a complete reply to the restriction/election of species requirement issued on February 3, 2009. In the event the Examiner requires any further information, or would like to schedule an interview to advance prosecution in this application, the Examiner is encouraged to contact Applicant's undersigned representatives.

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